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SEP 2 6 2008

Integrated Medical Systems, Inc.
1984 Obispo Avenue
Signal Hill, CA 90755

510(k) SUMMARY

The following summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. All data included in this document and are accurate and complete to the best of Integrated Medical System's knowledge.

Applicant:	Integrated Medical Systems, Inc. 1984 Obispo Avenue Signal Hill, CA 90755 (562) 498-1776
Contact:	Renate A. MacLaren, Ph.D. Director, Regulatory Affairs
Date:	August 5, 2008
Device Identification:	Common Name: Intensive Care Unit (ICU) Platform Physiological Monitor Ventilator Infusion Pumps
Trade Name:	Life Support for Trauma and Transport (LSTAT) G6 Lite
Classification Name(s):	Cardiac Monitor (21 CFR 870.2300, Product Code DRT) Continuous Ventilator (21 CFR 858.5895, Product Code CBK) Infusion Pump (21 CFR 880.5725, Product Code FRN)

Substantial Equivalence: The Integrated Medical Systems LSTAT G6 Lite is substantially equivalent to the Integrated Medical Systems LSTAT 9602 (K965117) since the basic features, design and intended uses are the same or similar. The differences in design, dimensions, and features between the LSTAT G6 Lite and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function, or intended use of the device.

Device Description: The Integrated Medical Systems LSTAT G6 Lite is a portable intensive care unit (ICU) for adult and pediatric patients. The LSTAT G6 Lite combines the medical device capabilities of a physiological monitor, a ventilator, and infusion pumps into a single platform with a central display.

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IMS

Intended Use: The LSTAT G6 Lite is a portable unit intended to supply ICU functionality for adult and pediatric patients. The LSTAT G6 Lite combines the following medical device capabilities into a single platform: Physiological monitoring (electrocardiogram, invasive pressure monitoring, non-invasive blood pressure monitoring, temperature, pulse rate, blood oxygen saturation, and heart rate), low rate and high rate infusion pumps, a fluid warmer, a ventilator with carbon dioxide monitoring capabilities, and the ability to deliver oxygen to a patient. The functions of the LSTAT G6 Lite are controlled from a central user interface. The LSTAT G6 Lite may be operated using either batteries or an external power source. The LSTAT G6 Lite is intended for use in hospitals, aircraft, ambulances, field hospitals, and extended care facilities.

Signed:

Renate A. MacLaren, Ph.D.
Director, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

Integrated Medical Systems, Inc.
c/o Renate A. MacLaren, Ph.D.
Director, Regulatory Affairs
1984 Obispo Avenue
Signal Hill, Ca 90755

Re: K082256
Trade/Device Name: Life Support for Trauma and Transport (LSTAT) G6 Lite
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: August 5, 2008
Received: August 8, 2008

Dear Dr. MacLaren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082256

Integrated Medical Systems, Inc.
1984 Obispo Avenue
Signal Hill, CA 90755

Indications for Use

510(k) Number (if known):

Device Name: **Life Support for Trauma and Transport (LSTAT) G6 Lite**

Indications for Use:

The Life Support for Trauma and Transport (LSTAT) G6 Lite System is a portable unit intended to supply intensive care unit (ICU) functionality for adult and pediatric patients. The LSTAT G6 Lite combines the following medical device capabilities into a single platform: Physiological monitoring (electrocardiogram, invasive pressure monitoring, non-invasive blood pressure monitoring, temperature, pulse rate, blood oxygen saturation, and heart rate), low rate and high rate infusion pumps, a fluid warmer, a ventilator with carbon dioxide monitoring capabilities, and the ability to deliver oxygen to a patient. The functions of the LSTAT G6 Lite are controlled from a central user interface. The G6 Lite may be operated using either battery power or an external power source. The G6 Lite is intended to be used in hospitals, aircraft, ambulances, field hospitals, and extended care facilities.

Prescription Use ___X___ **AND/OR** **Over-the-Counter Use**_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082256